UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

UNITED STATES OF AMERICA	)	
	)	
v.	)	**CRIMINAL NO. 2:22-cr-00132-NT**
	)	
MERIDETH C. NORRIS, D.O.	)	

DR. MERIDETH NORRIS' MOTION FOR JUDGMENT OF ACQUITTAL

NOW COMES Defendant, Dr. Meredith Norris, by and through Undersigned Counsel, and moves this Honorable Court to enter judgment of acquittal for the following reasons:

1. The Court may set aside a guilty verdict and enter an acquittal on the defendant's motion. Fed. Rule Crim. Proc. 29(c)(2).

2. Under Rule 29(c), Dr. Meredith Norris respectfully requests that the Court set aside the jury verdict and enter an acquittal.

3. In support of this Motion, Counsel attaches her Brief In Support of Her Motion For Judgment of Acquittal.

Dated this 3rd day of July, 2024 in Portland Maine.

Respectfully submitted,

/s/ Timothy E. Zerillo
Timothy E. Zerillo, Esq. (Bar No: 009108)
ZERILLO LAW FIRM, LLC
1250 Forest Avenue, Ste 3A
Portland, ME 04103
207-228-1139
tim@zerillolaw.com

/s/ Amy Fairfield
Amy Fairfield, Esq. (Bar No: 009598)
Fairfield & Associates, P.A.

10 Stoney Brook Lane
Lyman, ME 04002
207-985-9465
amy@fairfieldandassociates.com

Counsel for Defendant Dr. Merideth C. Norris, D.O.

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

UNITED STATES OF AMERICA	)	
	)	
v.	)	**CRIMINAL NO. 2:22-cr-00132-NT**
	)	
MERIDETH C. NORRIS, D.O.	)	

BRIEF IN SUPPORT OF MOTION FOR JUDGMENT OF ACQUITTAL

TABLE OF CONTENTS

INTRODUCTION

This is not a typical criminal case and this is not a typical post-verdict motion. It rests on concerns that go far beyond the fate of one physician. Here, federal law has let down not just Dr. Norris and her patients, but the recovery community in Maine and, indeed, the Nation. The Supreme Court tried to warn the prosecution, but it took little notice. The Government not only aided that failure in the law, but exploited it. The jury was given pieces to a jigsaw puzzle that, instead of providing clarity, provided a distorted view of the world of addiction and pain medicine.

Here the Court may focus entirely on the law as interpreted by the Supreme Court's recent decision in *Ruan v. United States*, 597 U.S. 450, 142 S. Ct. 2370 (2022). In *Ruan*, the defendants were medical doctors convicted under section 841 of the Controlled Substances Act ("CSA") for dispensing controlled substances other than "as authorized" under the statute. *Ruan*, 142 S. Ct. at 2375. Section 841 makes it a federal crime, "except as authorized, for any person knowingly or intentionally to manufacture, distribute, or dispense a controlled substance," such as opioids. *Id.* at 2374-75 (quoting 21 U.S.C. § 841(a)) (cleaned up). Under applicable regulations, a prescription is "authorized" when a licensed physician issues it "for a legitimate medical purpose acting in the usual course of his professional practice." *Id.* at 2375 (quoting 21 C.F.R. § 1306.04(a)) (alteration omitted). Crucially after *Ruan*, Section 841's "knowingly or intentionally" mens rea applies to the "except as authorized" clause of the regulations. 142 S.Ct. at 2382.

Accordingly, once a defendant produces evidence that she was authorized to dispense controlled substances, the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner—i.e., not "for a legitimate medical purpose acting in the usual course of his professional practice." *Id.* (alteration omitted).

The Government here was warned that "in § 841 prosecutions, a lack of authorization is often what separates wrongfulness from innocence"—particularly with respect to "doctors dispensing drugs via prescription." *Id.* at 2382. The Court rejected the notion that a conviction could be supported by "objectively reasonable good-faith effort" because that "standard would turn a defendant's criminal liability on the mental state of a hypothetical 'reasonable' doctor, not on the mental state of the defendant himself or herself." *Id.* at 2381. The Government might prove by reference to facts and circumstances surrounding the case that Dr. Norris, an authorized prescriber, knew that her conduct was unauthorized or illegal. However, the Government's showing of objective criteria, without proving that a defendant actually and subjectively intended or knew that she was acting in an unauthorized way, is not enough to support the conviction. Instead, the Government must prove, but did not, that she knew or intended that her conduct was unauthorized. *Ruan* told the prosecution what it must show, yet it was unable or unwilling to answer the call here. Instead, it provided exactly what *Ruan* said it could not: a solid and well-reasoned argument that convinced a jury that a reasonable doctor would not have done as Dr. Norris did and therefore it could (and did) convict her of criminal

charges. The Government ignored Justice Alieto's caution in his concurrence that acting "'as a physician' does not invariably mean acting as a good physician, as an objective understanding of the 'in the course of professional practice' standard would suggest. A doctor who makes negligent or even reckless mistakes in prescribing drugs is still 'acting as a doctor'—he or she is simply acting as a bad doctor." *Id*. at 2389.[1]

Prior to trial, Dr. Norris asked this Court to rule that the relevant sections of federal law, Section 841 of Title 21 of the United States Code, ("Section 841") was impermissibly vague as applied to her case. The Court denied the motion to dismiss on grounds of vagueness finding that it could not be decided without further factual development.[2]

Here these two concerns collide and become opposite sides of a coin, the specific burden to provide subjective intent provided to authorized prescribers in Section 841 prosecutions and the vagueness of the statute itself[3]. Dr. Norris was convicted without a showing that she could have known what she was doing was a crime. Dr. Norris was convicted without a showing that she intended to act in a way that was unauthorized. This outcome violates *Ruan*, due process and the

[1] Dr. Norris does not suggest that objective proof exists that she was reckless or negligent in issuing the prescriptions which are complained of in the Indictment. However, what appears to be clear is that based the jury confused the evidence that others disagreed with her choices and would have done something different as evidence of her shortcomings. Those inferred shortcomings are not sufficient for a conviction as Justice Alieto warned they would not be.

[2] The Court also warned the Government, if indirectly, of its burden of proof under *Ruan* that "[t]his case hinges on whether Dr. Norris 'knowingly or intentionally acted in an unauthorized manner' by prescribing controlled substances."

[3] This argument is explored in the Defendant's renewal of her vagueness challenge (namely *DEFENDANT'S MOTION TO VACATE VERDICT AND DISMISS FOR VIOLATION OF DUE PROCESS CLAUSE FOR VAGUENESS*) filed concurrently.

vagueness doctrine. Luckily this Court can correct these concerns with a Judgment of Acquittal.

Reduced to its essence, this motion asserts that contrary to *Ruan*, the jury was presented no evidence that Dr. Norris was subjectively aware her prescriptions were "unauthorized." The prosecution failed in its obligations to present relevant evidence sufficient to support the jury verdict.

ARGUMENT

A judgment of acquittal must be entered on each offense for which the evidence is insufficient to sustain a conviction. Fed. R. Crim. P. 29(a). When evaluating the sufficiency of evidence, the Court may draw the facts and all reasonable inferences therefrom in the light most agreeable to the jury verdict. *United States v. Williams*, 717 F.3d 35, 37-38 (1st Cir. 2013). The inquiry is whether any rational trier of fact could have found the essential elements of the crime beyond a reasonable doubt. *United States v. Rodríguez-Martinez*, 778 F.3d 367, 371 (1st Cir. 2015). While inferences must be "reasonable," "plausible" or "legitimate," *United States v. Smith*, 680 F.2d 255, 259 (1st Cir. 1982), this Court must determine whether the "body of proof, as a whole, has sufficient bite to ground a reasoned conclusion that the government proved each of the elements of the charged crime beyond a reasonable doubt." *United States v. Lara*, 181 F.3d 183, 200 (1st Cir. 1999) (citations omitted). The First Circuit has cautioned that "despite the prosecution-friendly overtones of the standard of review, appellate oversight of

sufficiency challenges is not an empty ritual." *United States v. de la Cruz Paulino*, 61 F.3d 986, 999 n. 11 (1st Cir. 1995).

The Court "must reject those evidentiary interpretations and illations that are unreasonable, insupportable, or overly speculative." *United States v. Spinney*, 65 F.3d 231, 234 (1st Cir. 1995). Where the evidence presented does not support the inference that a defendant had knowledge of the crime, the First Circuit "has consistently found the evidence insufficient." *Rodríguez-Martinez*, 778 F.3d at 371 (*quoting United States v. Pérez-Meléndez*, 599 F.3d 31, 42 (1st Cir. 2010)) (holding that "circumstantial evidence was not sufficient to convict because it did not adequately support the inference that appellants either actually knew about or were willfully blind to the controlled substances they were transporting"). In *United States v. Pérez-Meléndez*, a Section 841 case (but not involving authorized prescribers), the First Circuit reversed denial of motion to acquit in a similar posture to this matter: the Government had presented evidence from which a jury could (and did) infer knowledge of facts making defendants' conduct criminal. The district court determined that "the government provided sufficient evidence, including reasonable inferences, that when considered as a whole, warrant the jury's conclusion that the defendants were guilty beyond a reasonable doubt." *Id*. at 39 (citing to the trial court's order denying the motion). The appellate court reversed and ordered the trial court to enter a judgment of acquittal because, "proof of sufficient participation in the crime, *as well as knowledge of it*, is required to convict"; that the government must adequately prove knowledge, more so than

participation. *Id*. at 41 (emphasis added). "[C]ircumstantial evidence was not sufficient to convict because it did not adequately support the inference that appellants either actually knew about or were willfully blind to the controlled substances they were transporting within the pallets of reams of paper." *Id*. at 42.[4] The First Circuit found error from the trial court in analyzing what inferences were permissible:

> Some of the inferences the district court draws are certainly plausible, but their significance is limited. A rational factfinder could have drawn a plausible inference that appellants knew they were involved in an illegal activity because appellants' statements and omissions concerning their job and the manner in which they were hired for and performed that work earlier the same day are suspicious. However, we find that a rational factfinder could not have concluded beyond a reasonable doubt that appellants committed the charged crime because reasonable doubt should have remained that (1) appellants knew that the precise nature of that activity involved controlled substances generally or cocaine specifically and (2) appellants were aware of a high probability that illegal drugs were packaged within the pallets and consciously and deliberately avoided learning of that fact.
>
> As we have previously observed, "knowledge that one is guilty of *some crime* is not the same as knowledge that one is guilty of the crime *charged*." A significant body of case law from other circuits exists in which insufficiency of evidence was found where a defendant may have known he was participating in an illegal activity but there was little or no evidence to suggest that the defendant knew that the activity involved drugs specifically, and we adopt that position here.

Id. at 43, internal cites omitted.

Moreover, the stacking of inferences is equally impermissible. *United States v. Guzman-Ortiz*, 975 F.3d 43, 55–56 (1st Cir. 2020). In *Guzman-Ortiz*, the trial court granted a Rule 29 Motion after the jury's guilty verdict. *Id*. 45-46. There, the

[4] Much like this matter, as is shown *infra*, the Government only had circumstantial evidence regarding knowledge.

issue was whether a conspiracy to traffic controlled substances could be inferred from mere presence at the time of the drug activity. *Id*.

In upholding the trial court's setting aside of the jury verdict, the First Circuit noted that a judge may not "...stack inference upon inference in order to uphold the jury's verdict." *Id.* at 55. Further, and despite the defendant's presence at the scene of a drug raid where heroin was found, "We would have to engage in such impermissible inference stacking here to conclude not merely that "it is certainly possible -- maybe even probable -- that [Guzman-Ortiz] was involved in the conspiracy," but that there was "proof beyond a reasonable doubt" that he was." *Id* at 55 (internal citations omitted). Accordingly, "...we agree with the District Court that there is not sufficient evidence to permit a rational jury to find, beyond a reasonable doubt, that Guzman-Ortiz intended to join and effectuate the drug distribution conspiracy." *Id*.

Due Process forbids any conviction "except upon proof beyond a reasonable doubt of every fact necessary to constitute the crime with which the defendant is charged." *Jackson v. Virginia*, 443 U.S. 307, 315 (1979). Further, "a conviction based on speculation and surmise alone cannot stand." *United States v. D'Amato*, 39 F.3d 1249, 1256 (2d Cir. 1994). A reasonable jury cannot convict a defendant when the evidence gives nearly equal support to a theory of either guilt or innocence. *United States v. Ferguson*, 211 F.3d 878, 882-883 (5th Cir. 1995).

At trial the Government presented no evidence of Dr. Norris' subjective intent to commit the crime beyond a reasonable doubt.[5] While the Government presented what could be called inferences, these inferences are not evidence sufficient to sustain a conviction. That is true for a "simple" Section 841 case, *see*, *e.g.*, *Pérez-Meléndez*, 599 F.3d 31 (1st Cir. 2010), and thus certainly for this case which requires additional proof for a conviction.

As the Supreme Court in *Ruan* made clear, for a conviction to stand the scale has to be so far tipped far to the side of the unreasonable, past the center of the objective standard of care. *See Ruan* 142 S.Ct. at 2389 (Alito, J., concurring)("...A doctor who makes negligent or even reckless mistakes in prescribing drugs is still 'acting as a doctor'... the same cannot be said…when a doctor knowingly or purposefully issues a prescription to facilitate 'addiction and recreational abuse,'...a doctor who prescribes drugs for those purposes is not 'acting as a physician'..."). Absent the same, scienter is not established. *Ruan* at 2382 ("[a]s we have said before, 'the more unreasonable' a defendant's 'asserted beliefs or misunderstandings are,' especially as measured against objective criteria, 'the more likely the jury . . . will find that the Government has carried its burden of proving knowledge.'…But the Government must still carry this burden. And for purposes of a criminal conviction under §841, this requires proving that a defendant knew or intended that his or her conduct was unauthorized."). The Government

[5] Nor did the Government provide a motive for what it alleges were criminal violations. Lack of motive bears on the range of permissible conclusions that might be drawn from ambiguous evidence. *Matsushita Elec. Industrial Co. v. Zenith Radio Corp*., 475 U.S. 574, 597 (1986) ("if petitioners had no rational economic motive to conspire, and if their conduct is consistent with other, equally plausible explanations, the conduct does not give rise to an inference of conspiracy.").

wholly failed to meet its burden of proof. As the Supreme Court made clear, "A strong scienter requirement helps to diminish the risk of "overdeterrence," *i.e.*, punishing acceptable and beneficial conduct that lies close to, but on the permissible side of, the criminal line", and this Court—as the ultimate gatekeeper between a caring physician and a conviction—should set aside the verdict and acquit Dr. Norris.

A person may not knowingly or intentionally dispense a controlled substance without authorization. 21 U.S.C. §841(a). A controlled substance is deemed dispensed when prescribed by a "practitioner," 21 U.S.C. §802(10), which includes physicians permitted by federal or state law to dispense controlled substances in the course of professional practice. 21 U.S.C. §802(21).

It was stipulated at trial that Dr. Norris was a physician, properly licensed by the Maine Board of Osteopathic Medicine, and registered with the federal Drug Enforcement Administration ("DEA"). Once registered, a physician may dispense controlled substances to the extent authorized by the registration. 21 U.S.C. §822(b). Registration authorizes a physician to prescribe a controlled substance "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. §1306.04(a). Properly licensed and duly registered, Dr. Norris' prescriptions were valid and legal and remain so until shown otherwise here by proof beyond a reasonable doubt.

The question, then, is whether Dr. Norris prescribed certain controlled substances inside or outside the scope of her authorization, meaning whether she

knowingly or intentionally issued the challenged prescriptions for a legitimate medical purpose while acting in the usual course of her professional practice. *Ruan v. United States*, 597 U.S. 450, 142 S. Ct. 2370 (2022).

The CSA replaced the Harrison Narcotics Act and incorporated the settled understandings of the exemption discussed above given to doctors to dispense controlled substances in the course of professional practice. *Id.*, at 2389 (Alito, J., concurring) (discussing *United States v. Moore*, 423 U.S. 122, 139–140 (1975) (holding that the CSA carries forward the "usual course of practice" exemption for doctors found in the earlier Harrison Act)). Now, as then, "to act 'in the course of professional practice' is to engage in the practice of medicine" [—i.e.,] "to act 'as a physician.'" *Ruan*, 142 S. Ct., at 2389 (*citing Moore*, 423 U.S. at 141).

In *Ruan*, Justice Alito supplied a sensible definition for the practice of medicine in his concurring opinion: to "act for a medical purpose—which means aiming to prevent, cure, or alleviate the symptoms of a disease or injury—[to] believe[6] that the treatment is a medically legitimate means of treating the relevant disease or injury." *Id.* Although the justices in *Ruan* disagreed over whether authorization to dispense is an element of the offense or an affirmative defense—compare *Ruan,* 142 S. Ct., at 2382 (maj. op.), with *id.*, at 2383 (Alito, J., concurring)—they did not disagree on what it means to practice medicine. Compare *Ruan*, 142 S. Ct., at 2382 (maj. op.) (citing with approval *Gonzales v. Oregon*, 546 U.S. 243, 285 (2006) (Scalia, J., dissenting) (where Justice Scalia defined "medicine"

[6] To "believe" necessarily requires subjective intent: "I would thus hold that a doctor who acts in subjective good faith in prescribing drugs is entitled to invoke the CSA's authorization defense." *Id.* at 2389.

as "the science and art dealing with the prevention, cure, or alleviation of disease," *quoting* Webster's Second 1527)), with *Ruan*, 142 S. Ct., at 2382 (Alito, J., concurring) (supplying a materially identical definition).

Justice Alito also noted that the Supreme Court previously defined two objectives that are "alien to the practice of medicine" and would support criminal culpability: knowingly or purposefully prescribing controlled substances "to facilitate 'addiction or recreational abuse.'" *Id.*, at 2389 (Alito, J., concurring) (*quoting Gonzales*, 546 U.S., at 274). Neither of those objective criteria— meaning prescribing to facilitate addiction or recreational abuse— are present or inferred here.

Whether a defendant-doctor knowingly and intentionally[7] prescribed a controlled substance for a reason other than the prevention, cure, or alleviation of a disease or injury is the essential inquiry in a §841(a) prosecution. That inquiry is a subjective one. *Ruan*, 142 S. Ct., at 2381 (maj. op.) (holding that an objective standard does not apply). While the government may offer circumstantial evidence of the doctor's knowledge or intent by pointing to deviations from accepted standards and objective criteria, *id.*, at 2382, criminal liability does not, and cannot, turn on the "mental state of a hypothetical 'reasonable' doctor" or the defendant's deviation from what "his fellow doctors would view with medical care," *Id.*, at 238.

[7] "[T]he term ""knowingly' means that the act was performed voluntarily and intentionally, and not because of a mistake or accident." *United States v. Woodruff*, 296 F. 3d 1041, 1047 (11th Cir. 2002). The Model Penal Code states that one acts intentionally, with respect to an element of the offense relating to his conduct, when "it is his conscious object to engage in" that conduct. Model Penal Code § 2.02(1)(a) (defining "purposely"); Model Penal Code § 1.13(2) (stating that "intentionally" means "purposely"). Whether the word is "intent" or "purpose" what seems clear is that the defendant must be shown beyond a reasonable doubt to have as her objective to do the thing that is criminal.

The hypothetical "reasonable doctor" standard does not apply.[8] Again, it is "'the more unreasonable' a defendant's 'asserted beliefs or misunderstandings are,' especially as measured against objective criteria, [that] 'the more likely the jury . . . will find that the Government has carried its burden of proving knowledge.'… And for purposes of a criminal conviction under §841, this requires *proving that a defendant knew or intended* that his or her conduct was unauthorized." *Id.* at 2377-2378 (emphasis added). Notably, the district court in *Ruan* gave a "good faith" jury instruction, and the Supreme Court explicitly rejected the same, noting that words like "good faith," "objectively," "reasonable," or "honest effort" serve to "turn a defendant's criminal liability on the mental state of a hypothetical 'reasonable' doctor, rather than on the mental state of the defendant himself or herself." *Ruan* at 2381. That is what the Government did in this case and what this Court must correct. As, "The conduct prohibited…(issuing invalid prescriptions) is…"often difficult to distinguish from the gray zone of socially acceptable . . . conduct" (issuing valid prescriptions)" the Government repeatedly clouded this already difficult distinction to identify to the jury while also providing no evidence of Dr. Norris' subjective mental state to allow a finding of criminal liability. *See Ruan* at 2377-2378, citing *United States Gypsum*, 438 U. S., at 441.

[8] The Government can prove knowledge of a lack of authorization through circumstantial evidence. *Ruan* at 2382. Thus, *Ruan* offers confusing instructions for the Government and the courts. The surrounding facts that make a crime can be inferred but the intent remains entirely subjective and proof beyond a reasonable doubt is needed, proving that a defendant knew or intended that her conduct was unauthorized. *See Id.*

The text, structure, and legislative history of the CSA show that a doctor is authorized to issue a prescription if she does so in the course of professional practice. The only definition of "authorization" found in the CSA is that

> Authorized activities. Persons registered by the Attorney General under this title to manufacture, distribute, or dispense controlled substances ... are authorized to possess, manufacture, distribute, or dispense such substances ... to the extent authorized by their registration and in conformity with the other provisions of this title.

21 U.S.C. §822(b).

Though the scope of authorization is defined "in circular terms[,]. . . the scheme of the statute, viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of her 'professional practice.'" *United States v. Moore*, 423 U.S. 122, 140 (1975). "In the course of professional practice" is a legal term of art that traces back to the the Harrison Narcotics Act. *Id.*, at 132; *Ruan*, 142 S. Ct., at 2388 (Alito, J., concurring). The Supreme Court's "Harrison Act precedents interpreted that phrase to refer to 'bona fide medical practice,' which meant that any prescription issued 'in good faith' qualified as an authorized act of dispensing one of the drugs proscribed by the statute." *Id.* Justice Alito's concurrence in *Ruan* accurately described the meaning of the course of professional practice that was

carried into the CSA:

> Nothing in the CSA suggests that Congress intended to depart from the preexisting understanding of action "in the course of professional practice." We have previously held that the CSA incorporates settled understandings of "the exemption given to doctors" to dispense controlled substances "'in the course of ... professional practice'"under the Harrison Act. *Moore*, 423 U.S., at 139–140 (*quoting* 38 Stat. 786).

> And the language of the CSA supports the same conclusions that we previously reached about the Harrison Act. As our CSA precedents have explained, to act "in the course of professional practice" is to engage in the practice of medicine—or, as we have put it, to "act 'as a physician.'" *Moore*, 423 U.S., at 141. For a practitioner to "practice medicine," he or she must act for a medical purpose—which means aiming to prevent, cure, or alleviate the symptoms of a disease or injury—and must believe that the treatment is a medically legitimate means of treating the relevant disease or injury.
>
> But acting "as a physician" does not invariably mean acting as a good physician, as an objective understanding of the "in the course of professional practice" standard would suggest. A doctor who makes negligent or even reckless mistakes in prescribing drugs is still "acting as a doctor"—he or she is simply acting as a bad doctor. The same cannot be said, however, when a doctor knowingly or purposefully issues a prescription to facilitate "addiction and recreational abuse," *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006). Objectives of that kind are alien to medical practice, and a doctor who prescribes drugs for those purposes is not "acting as a physician" in any meaningful sense.

Ruan, 142 S. Ct., at 2389 (Alito, J., concurring) (parallel citations omitted).

Justice Alito's thorough analysis makes clear that CSA's authorization (and thus a physician's subjective intent) is not contingent on a practitioner acting within what other doctors might consider to be proper standards of medicine; what controls is the doctor's subjective purpose in issuing a given prescription. If the doctor wrote a prescription with the subjective purpose of treating a patient, she was within the course of professional practice and thus remained authorized to issue that prescription. Thus, for a prescription to be objectively unauthorized, the prescribing doctor must subjectively intend to issue it for a non-medical purpose.

This, of course, defines the very problem with this case. Dr. Norris cannot—by any measure and despite the Government's closing argument—be

reasonably described as a "drug dealer."[9] Any reasonable view of the evidence cannot be that Dr. Norris subjectively intends to facilitate "addiction or recreational abuse," which are the only clear parameters proscribed by the law. *Ruan*, 142 S. Ct., at 2389 (Alito, J., concurring). Notably, the regulatory language is "'ambiguous,' written in 'generalit[ies], susceptible to more precise definition and open to varying constructions.'" *Id.*, at 2377 (*quoting Gonzales*, 546 U.S., at 258), "meaning that prohibited conduct (issuing invalid prescriptions) is often difficult to distinguish from acceptable conduct (issuing valid prescriptions)." *Id.* at 2372 (internal quotation marks omitted). Allowing the vague regulation to define the scope of a doctor's prescribing authority runs afoul "the twin constitutional pillars of due process and separation of powers." *United States v. Davis*, 139 S. Ct. 2319, 2325 (2019).

I. SUMMARY OF PATIENTS AND COUNTS

Any attempt to summarize all the patient records and testimony here is fruitless. Yet, the Undersigned attempts to provide a high level overview of what was established at trial.

A. PATIENT 1, COUNTS 1, 6, 7, 8 AND 9

[9] Calling someone a "drug dealer" is purposefully inflammatory and can be prejudicial even when done during a closing argument. *See*, *e.g.*, Commonwealth. *v. LaCava*, 666 A.2d 221 (Pa. 1995). Aside from the vitriol, the phrase is inappropriate as used to label Dr. Norris because, the "dealer" part of "drug dealer" necessarily implies something the Government did not show—because it is untrue—that Dr. Norris profited from her issuance of prescriptions to Patients 1 through 5. A dealer is "dealer" is "a person or company that buys and sells things for profit:" https://dictionary.cambridge.org/us/dictionary/learner-english/dealer. Yet, the Government in closing indicated "And if you need more evidence with Patient 2 that Dr. Norris was acting more like a drug dealer than a doctor, I want you to remember what Patient 2 told you about his relationship with her." [T. 1532].

i. *Summary of Patient 1's Treatment*

Patient 1 presents as a 32-year-old male who has been under medical care for multiple complex health issues, which included:

- Chronic Pain: The patient has experienced chronic pain resulting from a past injury. GX 101:15.
- Motor Tics: Associated with trauma-induced Tourette syndrome. GX 101:15, 28.
- Mental Health: A variety of mental health issues were present. GX 101:49.

Patient 1's treatment included:

- Medication-Assisted Treatment ("MAT"):
  - The patient had MAT, which is tailored assistance to manage opioid dependence[10] often coupled with chronic pain management. GX 101:15.
  - There were discussions about increasing the dose of suboxone and transitioning to methadone for more effective pain relief. Methadone is frequently used in MAT for chronic pain because of its effective analgesic properties combined with its role in managing opioid dependence. GX 101:15.
  - The care plan is comprehensive and includes regular screenings and consultations to address the patient's chronic pain, motor tics, and mental health.

Overall, Patient 1's treatment involves a multi-faceted approach with a focus on effective pain management through potential use of methadone, coupled with

[10] MAT is treatment for addiction. *See, e.g., Metro Treatment Ctr. v. City of Bangor*, No. 1:16-cv-00433-JAW. D. Me. (Nov. 15, 2016) ("MAT is any treatment for addiction and COD [Co-Occurring Disorder] . . . MAT is intended to help stabilize addiction and COD symptoms."). As such it is nearly impossible to imagine a situation where MAT can be said to "facilitate addiction", *Gonzales*, 546 U.S. at 274, since the patient would already be addicted to something in order to qualify for the treatment. The Government presented no evidence that Dr. Norris' patients receiving MAT were not addicted to some substance prior to being given MAT.

stringent safety practices and monitoring to ensure the best outcomes for his various medical issues.

ii. *Counts Related To Patient 1*

a. Patient 1, Count 1, GX 1 (Methadone 12.23.21), Medical Record, GX 101

Dr. Norris prescribed methadone to the patient on October 19, 2021, primarily as a part of a MAT plan for managing the patient's chronic pain and potentially other co-occurring health conditions. There are specific details in GX101 that shed light on the considerations made by Dr. Norris in prescribing as she did:

- Chronic Pain Management: The patient has a history of chronic pain due to a past injury, and methadone was considered as an option for pain relief. The patient had ongoing complaints about pain in the back, although the pain in the ankle and knees was better managed. GX 101:15, 39, 58, 72, 86, 105, 138, 195, 216, 236, 269, 303, 312, 358, 386.

- Mental Health & Stability: The patient's recovery journey was noted to be stable. He was seeing a mental health professional weekly and had an optimistic outlook about moving out of his current living situation. GX 101:72, 186, 195, 269, 312.

- Safety Considerations: There was a caution highlighted about the use of benzodiazepines in combination with methadone. Dr. Norris explicitly communicated that benzodiazepine use needed to stop to safely continue methadone treatment. GX 101:72, 138, 290.

The indications for the effectiveness of methadone shortly prior to the October 19, 2021 prescription can be inferred from the patient's medication history and overall medical context. Notably,

- Transition from Suboxone: There was an ongoing discussion about increasing the dose of suboxone and transitioning to methadone. This suggests that methadone was being considered as a potentially more

effective option for managing the patient's pain and other symptoms. GX 101:15, 39, 58, 105, 138, 150, 269, 312, 358.

- Chronic Pain Management: The patient has a well-documented history of chronic pain resulting from a significant past injury. The consideration of methadone was specifically for pain relief, indicating its potential effectiveness in addressing the patient's chronic pain more efficiently than the current treatment. *Id*.

- Motor Tics and Tourette Syndrome: The patient's motor tics, related to trauma-induced Tourette syndrome, were another factor under consideration. The transition to methadone was considered beneficial in managing these symptoms as part of a comprehensive treatment plan. GX 101:15, 28.

In summary, the indications for the effectiveness of methadone shortly before the Count 1 prescription included its potential superior efficacy in managing chronic pain and possible efficacy over associated symptoms like motor tics. As the records make clear "Patient has chronic facial and neck motor tics…unable to control them. they are worse with pain flareups and anxiety." GX101.2. The decision was made to transition from suboxone to methadone based on these considerations and the patient's overall treatment history. Dr. Norris' decision to prescribe methadone on October 19, 2021 "to prevent…or alleviate symptoms", *Ruan*, 142 S. Ct., at 2389 (to "act for a medical purpose—which means aiming to prevent, cure, or alleviate the symptoms of a disease or injury—[to] believe that the treatment is a medically legitimate means of treating the relevant disease or injury."), was tailored to the patient's chronic pain and overall health management needs inclining significant substance abuse and addiction, while emphasizing safety and stability in the treatment plan.

b. Patient 1, Count 6, GX 6 (Methadone, 2.21.22), Medical Record,

GX 101

Dr. Norris prescribed methadone on February 21, 2022, based on specific prior considerations relating to its anticipated effectiveness for the patient. Here are the main points that justified the necessity of this prescription:

- Chronic Pain Management: The patient had been dealing with chronic pain due to a past injury. The ongoing discussion about transitioning from suboxone to methadone for better pain relief suggests that methadone was expected to provide more effective pain management. GX 101:15, 39, 58, 72, 86, 105, 138, 195, 216, 236, 269, 303, 312, 358, 386.

- The patient continued in MAT. Methadone is commonly used in MAT for its dual efficacy in treating chronic pain and aiding opioid dependence recovery. This fits within the broader treatment plan to provide comprehensive care. GX 101:15.

- Communication with Pharmacists: A message between medical personnel indicated that there was a conversation concerning the patient's history of methadone use. This interaction highlights the scrutiny and clinical oversight in place, which confirms the appropriateness of methadone as part of the treatment plan. For example, at GX 101:214:

[redacted] 214

Graceful Recovery
58 Portland Rd #18, Kennebunk, ME 04043
Office: 207-604-5034; Fax: 207-604-5038

Office Message

Patient Name: Patient 1
D.O.B.: [redacted] 35 yrs, 6 mo at the time of printing this document
Gender: Male
Patient ID: [redacted]
Cared for by Merideth Norris, DO

Message between Merideth Norris, DO, Nancy Drown, Barbra Courtois

09/04/2020 1:11 pm **Barbra Courtois**
[redacted] jeff from bidd/cvs states pt. was talking to pharmacist last night on how long he's been clean. pharmacist wants a call asap. they are uncomfortable filling his methadone & won't until you have a conversation. script says for acute pain, but they think you may be treating him for addiction

09/04/2020 3:27 pm **Merideth Norris, DO**
Spoke with pharmacist. He is being treated for traumatic arthropathies and yes he is in recovery and he is probably conflating those in his mind but no I'm treating pain.

In summary, Dr. Norris deemed methadone necessary for its effectiveness in managing the patient's chronic pain, its structured use within the MAT program, and the established surveillance ensuring its safe prescription. This comprehensive approach ensured that the medication was both necessary and appropriately monitored.

c. Patient 1, Count 7, GX 6 (Diazepam, 2.21.22), Medical Record, GX 101

Dr. Norris prescribed diazepam shortly before the February 21, 2022, prescription based on several factors, as indicated in the provided medical records (GX 101):

- Management of Motor Tics: Patient 1 suffers from motor tics associated with trauma-induced Tourette syndrome. Diazepam, which is a benzodiazepine, is often prescribed to manage muscle spasms and alleviate the severity of motor tics. GX 101:15, 28.

- Mental Health Consideration: Diazepam is also used to address anxiety and other related mental health issues. Given the comprehensive treatment plan that includes regular mental health status checks, diazepam was seen as beneficial in managing these symptoms. GX 101:358.

These factors combined suggest that Dr. Norris prescribed diazepam to effectively manage motor tics and associated anxiety, forming part of the broader, carefully monitored treatment plan for Patient 1 when the medical history before Dr. Norris was clear that Patient 1's tics are "worse with pain flareups and anxiety" requiring medication to prevent or alleviate the symptoms of the disease or injury. GX 101.2; See *Ruan,* 142 S. Ct., at 2389. (*see* GX101:358 on February 3, 2022, "Continue diazepam although I continue to reiterate that the goal is to reduce the med load. His life has not been stable in months and it is difficult to get any

changes going."). Dr. Norris' subjective criminal intent is not shown by these records or this history of treatment, in fact just the opposite.

d. Patient 1, Count 8, Methadone, 3.21.22, Medical Record, GX 101

Dr. Norris prescribed methadone for Patient 1 on March 21, 2022, for the following reasons:

- Chronic Pain Management. GX 101:15, 39, 58, 72, 86, 105, 138, 195, 216, 236, 269, 303, 312, 358, 386.

- Patient's History and Condition: The patient has a long-standing history of chronic pain due to multiple traumatic injuries, including a serious injury to the lumbar spine and hip, which required a hip replacement. This chronic pain has been a significant and persistent issue since a motor vehicle accident in 2009. Methadone was considered a potentially more effective option for managing this chronic pain compared to other medications. *Id*.

- Integrated Pain and Addiction Management: As part of the MAT plan, Methadone is used both for pain relief and to treat opioid addiction, making it suitable for patients with complex needs such as managing chronic pain while also addressing opioid dependency issues. GX 101:15.

- Treatment Discussions: There were previous discussions about switching from suboxone to methadone, with the patient expressing this preference thinking it might be more effective for both pain relief and opioid replacement therapy. This indicates a collaborative and informed decision-making process between the patient and Dr. Norris. For example, Patient 1's records from his referring doctors references this decision was reasoned and was at least in part made prior to Dr. Norris' involvement:

3. motor tics
Patient has chronic facial and neck motor tics from trauma induced Tourette syndrome. He has been unable to control them. they are worse with pain flareups and anxiety. Was started on Guanfacine a few weeks ago and has noticed no improvement. He tried Haldol prior to that and had horrible side effects. He reports that Librium is the most effective. He was prescribed this while incarcerated. He has been taking this intermittently. Does not have an Rx, but obtaining through a friend.
4. chronic pain
Patient has chronic pain due to MVA in 2009. he was in a coma for several weeks, had serious injury to lumbar spine. R hip, had to have R hip replaced. had to go through months of PT and relearn how to walk. he would like a referral to Dr. Kaufman for pain management. he is considering switching from Suboxone to Methadone, thinking this would help with both opiate replacement but particularly pain relief.

GX101:2.

- Past Prescriptions and Monitoring: Methadone was previously prescribed, and records from earlier encounters reflect that the patient had been using methadone under close monitoring by a physician. The prescription on March 21, 2022 continued this treatment approach, providing consistent and monitored pain management and MAT.

The prescription of methadone on March 21, 2022, was based on the patient's chronic pain condition, the dual need for pain and addiction management, previous successful discussions and assessments by other health professionals, and consistent monitoring to ensure safe and effective treatment. This comprehensive and patient-tailored approach was "a medically legitimate means of treating the relevant disease or injury" aimed at preventing or alleviating symptoms of Patient 1's disease or injury to improve the patient's overall quality of life. *Ruan*, 142 S.Ct. at 2389.

e. Patient 1, Count 9, Diazepam, 3.21.22, Medical Record, GX 101

Dr. Norris prescribed diazepam on March 21, 2022, for Patient 1 based on several underlying health considerations and aspects of the patient's medical history:

- Chronic Pain and Muscle Spasms: Diazepam is often used as a muscle relaxant. Given the patient's chronic pain issues, particularly related to a history of severe injury and ongoing pain management, diazepam would help alleviate muscle spasms associated with his condition.

- Mental Health and Anxiety Management: Diazepam is also prescribed for the treatment of anxiety, which can be related to the patient's overall mental health condition. The patient has a history of trauma-induced symptoms, including motor tics, which could contribute to increased anxiety.

- Motor Tics: The records are clear that Patient 1's motor tics are "worse with pain flareups and anxiety". GX101.2. Diazepam as prescribed also assists to prevent or alleviate both Patient 1's pain as a result of muscle spasms as well as, his anxiety which also treated his motor tics by preventing or alleviating "flare ups" that made them worse. GX 101.2; *see Ruan,* 142 S. Ct., at 2389.

- Previous Prescriptions and Clinical Efficacy:

    - There are records of prior prescriptions where Dr. Norris had prescribed a combination of methadone and diazepam and the patient tolerated them well:

        - December 23, 2021: Methadone and Diazepam, CVS.

        - January 10, 2022: Methadone, Diazepam and Fioricet, Walgreens.

        - Integrated Care Approach: This prescription on March 21, 2022, fits within an established treatment framework aiming to cover multiple aspects of the patient's health, including pain management, motor tics, and mental health.

Dr. Norris' prescription of diazepam on March 21, 2022, for Patient 1 was a considered decision to manage muscle spasms, alleviate anxiety related to chronic pain and motor tics, manage anxiety that increases motor tics, and continue a well-documented and partly pre-existing treatment strategy involving both methadone for pain and diazepam for additional therapeutic effects.

By consistently monitoring the patient's overall health status and adapting treatment plans as necessary, this approach aims to provide comprehensive and effective care. There is no evidence Dr. Norris subject to intent was to do anything except to act as a physician attempting to prevent or alleviate Patient 1's symptoms of his disease or injury.

B. PATIENT 2, MICHAEL MURPHY, COUNTS 3, 4 AND 5

i. *Summary of Patient 2/Murphy's Treatment*

Medical Conditions:

- Liver Issues: Including a liver mass and cirrhosis. GX102:2.
- Hepatitis B: Current. GX102:13.
- Hepatitis C: Successfully treated with a 12-week course of Harvoni as of November 2017. GX102:2.
- Cocaine Use Disorder. GX102:2, 460.
- Neuropathy. GX102:480.
- Substance Abuse History: Including opiate abuse and treatment with Suboxone. GX102:80.
- Smoking History.

Treatment Plan:

- Follow-Up and Monitoring:
    - Dr. Norris actively monitored the patient's liver health and addressed the complex medical issues associated with it. GX102:2, 13, 147.
    - The patient's progress was tracked through regular follow-ups to manage and coordinate care effectively.
    - The patient had a history of opiate abuse and was provided substance abuse treatment. GX102:34, 91, 115, 190, 565.

- The detailed plan underscores the significance of compliance with medication and appointment schedules to ensure effective management of the patient's health conditions.

This comprehensive treatment approach aimed to address the patient's multifaceted medical issues including prescribing medication to prevent or alleviate symptoms of his disease, and focusing on sustained health improvement through diligent monitoring and adherence to prescribed protocols.

ii. *Counts Related To Patient 2*

a. Patient 2, Count 3, Oxycodone, 12.23.21, Medical Record, GX 102

Far from acting as a drug pusher, Dr. Norris met with Patient 2 after his suicide attempt by taking his CAP Quality Care take home methadone medication. Her patient record suggests an intent to provide honest medical services to a patient in crisis.

Problem:
We had learned that [redacted] had been in crisis and had ingested his takehome bottles of methadone in addition to what was reported as 6 clonazepam. He says he was in a bad place, is getting into dual diagnosis treatment and has more support. He does continue to perseverate on how it was no 6 clonazepam, he just took one or two but the reality is that this is not the important thing, it was that he was suicidal and was not safe with his medications. The methadone clinic has him on daily dosing now. He recognizes that there were issues involving his ongoing cocaine use and that his partner did not want him around his son and this was what set him off. He knows things need ot be different. He continues to have rectal pain and has not been able to get all of that resolved surgically, many things are still pending and obviously managing that was the least of his concerns.

GX102:460.

By focusing on pain relief for specific dental issues, the prescription of oxycodone was aimed at managing through prevention or alleviation of significant discomfort while also recognizing and addressing Patient 2's co-occurring treatment of opioid substance use disorder through CAP Quality Care, by only prescribing in

limited amounts. *See* GX102:460 ("Oxycodone for the pain in limited amounts at a time.").

b. Patient 2, Count 4, Dextroamphetamine-amphetamine, 12.23.21, Medical Record, GX 102

Patient 2, was prescribed dextroamphetamine-amphetamine (commercially known as Adderall XR) on December 23, 2021, for the management of Attention-deficit/hyperactivity disorder ("ADHD"). The relevant information from the patient's medical file highlights:

- Medication and Dosage:
    - The patient was prescribed Adderall XR 20mg.
- Prescription Process and Rationalization:
    - There is mention of a consideration to switch to Vyvanse (a different medication for ADHD). GX102:460
    - The request for Adderall XR was being evaluated, indicating ongoing management and optimization of ADHD medication.
- Medical Testing and Monitoring:
    - Consistent results were reported from medical tests showing that the patient had positive results for amphetamine, aligning with the prescribed medication (Adderall XR) intake. GX102:460 ("Continue stimulant. He is getting a lot done and having good executive function. He gets tox tested quite a bit between here and the methadone clinic.)

This prescription was part of a treatment plan to address ADHD symptoms, taking into consideration patient compliance and the efficacy of the medication under the scrutiny of healthcare providers.

c. Patient 2, Count 5, Clonazepam, 12.23.21, Medical Record, GX 102

Patient 2 was prescribed clonazepam on December 23, 2021, primarily due to a mental health crisis and specific circumstances surrounding his situation at the time. The detailed encounter notes provide the reasoning for the prescription:

- Mental Health Crisis:
    - The patient was experiencing significant psychological distress, partially due to issues involving ongoing cocaine use and relationship problems. GX102:460.
- Dual Diagnosis Treatment:
    - In response to his crisis, there were plans for the patient to get into dual diagnosis treatment, addressing both substance abuse and mental health issues. GX102:460.
- Medication Management:
    - Clonazepam (a benzodiazepine) was already part of his medication regimen, although the exact dose taken by the patient was uncertain. He recounted taking fewer tablets than reported, but the critical concern was his safety and level of supervision with medications.
    - The patient was not safe with his medications during this crisis, leading to tighter control measures from the methadone clinic which moved him to daily dosing as well as, Dr. Norris reducing his dose of clonazepam GX102:460 ("Lower dose clonazepam - I'm not keeping you at the same dose as before you are not showing safety.").
- Psychosocial Factors:
    - There were significant social stressors well beyond his or Dr. Norris' control, including his partner's refusal to let him see his son, contributing to his mental health crisis[11]. GX102:460.

[11] Note also that this took place days before Christmas, a difficult time for many people. https://www.nami.org/from-the-ceo/the-most-difficult-time-of-the-year-mental-health-during-the-holidays/ ("64% of people with mental illness say the holidays make their conditions worse. A 2021 survey showed that 3 in 5 Americans feel their mental health is negatively impacted by the holidays.")

- The patient showed awareness of his need for change and more support. GX102:460.

Given these circumstances, the prescription of clonazepam was to help manage severe anxiety and distress during a mental health crisis when Patient 2 clearly needed medical assistance including medication to stabilize him. What he did not need was his physician to abandon him. The patient's self-reported intake underscored the immediate need for closely monitored medication management and comprehensive treatment for both mental health and substance abuse issues. This prescription was part of a broader treatment strategy to stabilize the patient and provide support for his dual diagnosis treatment.

iii. *Patient 2/Murphy's Testimony*

Mr. Murphy got hooked on drugs in the Youth Center at 16 years old. [T. 1300]. At the age of 19, he was at CAP Quality Care, being prescribed between 220 and 240 milligrams of methadone per day. [T. 1301]. He was left to resort to heroin. [T. 1304]. He tried to get into the Mercy Rehab Center (now closed), but could not make it through the three days to fully detox. [T. 1303-1304]. This led him in search of a suboxone doctor, landing him at the doorstep of Dr. Norris in 2003. [T. 1305-1306]. While he was ultimately discharged from her practice, he found Dr. Norris again in 2017, and began treating with her once again.

Ultimately, Mr. Murphy experienced sobriety for four years under Dr. Norris' care, from 2017 through 2020. As we heard, however, he attempted suicide at the end of 2021. Dr. Norris did not simply prescribe him drugs thereafter, rather she

treated him holistically and avoided prescribing him controlled substances. As he described it:

> Q. And did you -- at that point when you're in the hospital and you're now back to consciousness, did you have any problems with withdrawals?
> A. With the benzos, yes.
> Q. And did you -- did you contact Dr. Norris' office?
> A. I tried, you know.
> Q. What do you mean by that?
> A. Well, I tried to call. I sent messages, you know, and they know how -- when I say them, I say Dr. Norris and her medical assistant know me very well because they've been dealing with me for lots of years… And I was like, you know, I want my meds, you can't do this to me, like, this is against the law. Like, you know. You know, because I was in rough shape, like I was -- I was hurting.

[T. 1334].

Further, Nancy Drown, Dr. Norris' medical assistant called Murphy, indicating:

> A. Michael, you have to wait until you have your doctor's appointment because we cannot give you a script of Klonopin when you just drank 500 milligrams of methadone and almost died…
> Q. And so did Dr. Norris stick with that until she saw you?
> A. Yes.

[Tr. 1334-1335]

In sum, the evidence presented about Dr. Norris' treatment of Murphy cannot establish her subjective intent to act outside of her authorization beyond a reasonable doubt. Quite the opposite: her refusal to simply prescribe controlled substances- disappointed Murphy and negated any possible inference the Government might have relied on. More importantly, as Mr. Murphy stated in his own words, "She saved my life, on numerous occasions." [T. 1343]. There is simply

no evidence that Dr. Norris's subjective intent in prescribing controlled substances was "to facilitate 'addiction or recreational abuse.'" *Ruan,*at 2389 (Alito, J., concurring) (*quoting Gonzales*, 546 U.S., at 274).

C. PATIENT 3, BARBARA COURTOIS, COUNT 10

i. *Summary of Patient 3/Courtois's Treatment*

Patient History and Assessment:

- The patient presented as a 49-year-old female with a history of heavy alcohol use spanning 20 years, consuming alcohol 3 to 4 times a week. GX103:3. Patient also had chronic back, neck and shoulder pain.

Treatment and Plan of Care:

- The treatment plan includes several modalities for managing the patient's condition:
    - Body Mechanics: aimed at improving the patient's physical condition and addressing any musculoskeletal issues. GX103:3
    - Osteopathic Manipulation aimed at improving the patient's back pain, neck and shoulder as part of a comprehensive rehabilitation plan. GX103:3, 536, 56, 58, 61, 165, 397, 816, 849.

ii. *Count 10 (Fentanyl, April 8, 2022) Related To Patient 3*

Dr. Norris prescribed Patient 3 for a long period of her treatment, beginning in September of 2019. [T. 1457]. The charged prescription was consistent with an ongoing pain management regimen overseen by Dr. Norris, related to the patient's extensive medical history which includes factors like alcohol-related liver assessment and chronic pain issues.

iii. *Barbara Courtois Testimony*

Courtois first saw Dr. Norris in 2014:

A. I first saw her I believe it was at Southern Maine Healthcare.

> Q. Okay.
> A. And I'd been a patient there and the doctors kept cycling through and she was starting her own practice and I'd seen her there a few times. And I asked her if I could follow her to her new practice and she said yes.
> Q. Okay. And that was in around 2014; is that right?
> A. I'm really not clear on the date, but it was -- yeah. It was quite a while ago.
> Q. About eight or nine years ago?
> A. Anyway, yeah.

[T. 1424].

Courtois had been diagnosed with spinal stenosis prior to seeing Dr. Norris. [T. 1425]. Courtois described this as a painful condition. *Id.*

Courtois had numerous problems as described above, calling herself a "bad patient". [T. 1444; 1452]. Regarding the charged fentanyl, it is worth noting that this was long prescribed before the April 8, 2022 count for this patient.[12] As the patient indicated,

> Q. Okay. Do you recall when Dr. Norris put you on the fentanyl patch?
> A. Yes.
> Q. And it looks to be the end of September of 2019; is that right?
> A. Yes.

[T. 1457].

The fentanyl patch worked well for Patient 3. She testified:

[12] It is within the purview of the Government to charge a single prescription over the course of years of treatment. However, presenting it as the Government did, undermined the intent of *Ruan* to have a doctor defendant evaluated within the framework of her own subjective understanding of the patient's needs. *Ruan*, 142 S. Ct. at 2371 (Section 841's overt "knowingly or intentionally" mens rea applied to the statute's "except as authorized" clause). First, in Section 841 prosecutions, "a lack of authorization is often what separates wrongfulness from innocence." Id. 2377. Because of Section 841's unique, burden-shifting framework a defendant who is otherwise authorized to dispense controlled substances, such as a doctor, first produces evidence that his conduct was authorized, at which point the burden shifts back to the Government. Once a defendant has met his burden, her conduct is presumptively legal. Thus by isolating one prescription from the series, the Government has added to its burden of proof. Here it could not carry that burden and a judgment of acquittal is appropriate.

> Q. And how does a fentanyl patch work?
> A. Well, the good thing about it is you don't have to take pills and you don't have to take -- excuse me -- take them on time. You put on a patch, and you have to be very careful, wash your hands, you don't want to, you know, smear it on the counter or anything… But you put on the patch, and then you just leave it on and it gives you the right dose of medication so you don't have to worry about what time it is and what pills to take. It was a life changer.
> Q. Okay. Tell me about that. How was it a life changer for you --
> A. Immediate.
> Q. -- other than not having to take pills?
> A. Because it was the one thing that seemed pretty consistent on keeping down the pain, and it -- it just -- it worked very well for me.

[T. 1458].

Patient 3 was on the fentanyl patch for two and a half to three years. [T. 1459]. Her team of physicians knew she was on the fentanyl patch. *Id*. Her condition worsened when she stopped taking the fentanyl patch. [T. 1462]. She testified that prior to Dr. Norris' arrest "I feel like I was on the perfect dose of fentanyl." [T. 1463]. After she lost access to the fentanyl, the pain came back:

> A. Oh, when you stop taking it you can have horrible withdrawal symptoms and be sick. And when I didn't have it anymore I didn't experience all that.
> Q. Okay. You didn't get sick?
> A. No.
> Q. Okay. And did you experience other unpleasantries when you stopped putting on the fentanyl patch?
> A. No, nothing as far as reactions to having withdrawals or anything. It was just slowly the pain just started coming back and --
> Q. Are you -- as you sit here today, are you limited in the things that you can do?
> A. Absolutely…
> Q. And since -- since you've stopped the fentanyl patch, have you had subsequent hospitalizations?
> A. Yes.

[T. 1463-1464].

Patient 3 was difficult and complicated. She was, as she testified, "horrible with taking medications" and was "…a bad patient." [T. 1444; 1452]. Dr. Norris' subjective intent to act outside her authorization cannot be met by the medical records or this history of treatment. Because in this case the only charge regarding Patient 3 was a single prescription and the jury was presented evidence that clearly showed the medical value of the prescription (by its absence), no reasonable jury could have found Dr. Norris guilty on this count because of the additional scienter required by *Ruan*. The evidence was overwhelming that Dr. Norris prescribed the fentanyl patch to prevent or alleviate the symptoms of Patient 3's disease or injury and, in fact, it did so. The confusion came from how the Government charged a single prescription from among a series of medications.

F. Patient 4, Counts 12, 13 and 14

i. *Summary of Patient 4's Treatment*

- Treatment Duration:
    - Dr. Norris provided care for Patient 4 for approximately five years. GX104. Clearly, this was another legacy patient.
- Complex Medical History:
    - Patient 4 was characterized as incredibly complex and high-risk, with extensive medical records exceeding 1,700 pages. GX104. Patient 4 had a severe history of multiple traumas, including childhood abuse, multiple head injuries, physical trauma, and a complex chronic pain syndrome. [T. 1211].
- Behavioral and Social Challenges:
    - Described as very self-destructive, Patient 4 struggled with substance abuse and also faced numerous real world barriers such as unstable

housing, lack of transportation, and difficulty keeping medical appointments. [T. 1212]

- Referral to Dr. Norris:

    - Referred to Dr. Norris by Dr. Kathryn Brandt, who identified Dr. Norris' unique qualifications in managing complex cases due to her expertise in osteopathic manipulative medicine, pharmacological management, and addiction medicine. [T. 1210].

ii. *Dr. Brandt's Testimony About Referral of Patient 4 To Dr. Norris*

While Patient 4 did not testify, her referring physician, Dr. Brandt, did. Dr. Brandt, a doctor of osteopathy and also professor at the University of New England School of Medicine noted:

> No, I very specifically identified Dr. Norris as being uniquely qualified to manage this patient's care (Patient 4), both for her expertise in osteopathic manipulative medicine and its incorporation into pharmacologic management of issues, as well as her additional certification in addiction medicine, which I did not have. I was also concerned, given the complexity of this patient and her psychosocial issues, that she would be lost to care if she stayed in the practice that I was leaving.

[T. 1210].

That complexity was exactly why Dr. Brandt chose Dr. Norris for the referral. She noted:

> I think when someone has been through the kind of trauma that this patient has been [through], they have a very difficult time articulating themselves. They have a very difficult time with trust, particularly of people of authority or with degree and oftentimes following through on instructions or engaging in things that they need to do to help themselves. And Dr. Norris is most able to be in that, to have those difficult conversations, to remain present and able to meet a patient where they are at to establish that trust and bring them forward. So unlike many of my colleagues in that practice who would have come up

> with a way to fire her for difficult behaviors, I knew that Merideth -- Dr. Norris would not.[13]

[T. 1213].

As Dr. Brandt described, Patient 4 had a complex medical etiology:

> The basis, as I recall, was legion. There was not any one specific event. She had a very severe history of multiple traumas and abuse from childhood, multiple head injuries. I believe there were some other mechanical traumas in there, but I don't recall the details of those. So she had a very complex chronic pain syndrome, as well as a complex post-traumatic stress syndrome.

[T. 1211].

This "legion" of problems further informed Dr. Brandt's referral to Dr. Norris:

> Q. Did you have any concerns with giving Patient 4 to Dr. Norris?
> A. I did not.
> Q. Did you understand that Dr. Norris had a background in the MAT, the medicine-assisted treatment programming?
> A. Yes.
> Q. Did you also understand that she had a background dealing with the homeless population?
> A. Yes.
> Q. The mental health population?
> A. Yes.

[T. 1213].

Further, Dr. Brandt indicated that Patient 4 had various barriers to care. Notably,

> She did not have stable housing most of the time. She did not have transportation. She had struggled with keeping appointments in multiple different kinds of practices, you know, medical psychology,

[13] Kathryn Brandt exercised independent judgment that the Government's medical expert Timothy King did not: recognizing that Dr. Norris' subjective care of patients necessarily differs from that of a "common" doctor due to her extra extra training and years of experience.

> dental was a big problem that she had, and she had had trouble accessing care with those facilities.

[T. 1212].[14]

In the end, Dr. Brandt had no concerns or regrets related to her referral to Dr. Norris. [T. 1220)]. Notably,

> Q. If you learned that Dr. Norris had prescribed benzos to Patient 4, would you have trusted -- do you trust her judgment?
> A. Yes.
> Q. And if you learned that Dr. Norris prescribed methadone for a series of years, did you trust her judgment?
> A. Yes.

[T. 1225].

Dr, Norris' treatment of Patient 4 was careful and considerate, despite being presented with a patient with myriad problems. Evidence beyond a reasonable doubt regarding Dr. Norris' *mens rea* to operate beyond her authorization was never presented and could not be inferred by the jury.

E. PATIENT 5, COUNTS 10, 15 AND 16

i. *Summary of Patient 5's Treatment*

Referral Request: Patient 5 was referred from Dr. Gary Winn, MPH, DO. GX105:6. His treatment is summarized as follows:

- Substance Use Disorder and Non-Compliance: Patient 5 had been using controlled substances such as methadone, hydromorphone, and fentanyl, long

[14] The Government presented no evidence at all, thus certainly not any from which the jury was entitled to infer, about how Patient 4's real life challenges could impact the appropriate care that Dr. Norris was entitled to be presumed to have given. While Dr. King opined generally how Patient 4 should have been treated, his testimony was not sufficient as a basis for a conviction given the *Ruan* framework. That Dr. King disagreed with Dr. Norris' treatment of Patient 4—or any of the relevant patients—does not show a subjective *mens rea* nor is it sufficient to allow for the inference of subjective mens rea in light of *Ruan*. No evidence was presented to cure this concern and therefore the jury could not have found Dr. Norris guilty.

before being treated by Dr. Norris. However, these substances were not always being used as prescribed, leading to concerns about non-adherence and potential misuse.

- Treatment Duration: Patient 5 was a referral from 2017, but did not engage Dr. Norris until 2022. GX105:1. Patient 5 treated with Dr. Norris for four months.

- Chronic Pain Issues and Chronic Health Conditions:

    - Spinal Stenosis and Foot Pain: Persistent pain due to spinal stenosis and unresolved issues from a previous foot surgery have been major concerns for the patient. Despite being on pain management plans, including opioids, the pain control has been insufficient.

    - On March 3, 2022, Dr. Norris reviewed PMP, and noted Patient 5 had been receiving prescriptions for diazepam and oxycodone, last filed in December of 2021 for 240 pills of oxycodone. Dr. Norris will only give Patient 5 a one week supply. GX105:11.

    - Diabetes Mellitus Type 2 ("DM2"): Patient 5 has been diagnosed with DM2 and was under treatment, including with medications including metformin and Januvia. Regular monitoring and lab tests were used to manage this condition effectively. GX105:12, 171, 176.

    - Hypertension: The patient has hypertension, which needed ongoing medical attention and medication to manage blood pressure levels. GX105:11, 176.

- History of ADHD and Obesity:

    - ADHD: The patient is diagnosed with Attention Deficit Hyperactivity Disorder ("ADHD") and was receiving treatment for the same. GX105:11, 176.

    - Obesity: Obesity was a persistent problem for Patient 5, necessitating weight management and lifestyle modification programs.

- Mental Health and Social Issues:

    - Mental Health: Apart from physical ailments, the patient had been dealing with mental health issues related to the chronic pain and substance use disorders. GX105:176.

- Social History: The patient's social history includes tobacco use and a family history of alcohol misuse and various cancers. These complicated the prognosis and treatment compliance. GX105:176.

These highlighted problems illustrate the complexity of Patient 5's health status, requiring a multidisciplinary and coordinated approach to manage the chronic health conditions, health risks and the substance use disorder effectively and simultaneously.

ii. *Counts Related To Patient 5*

a. Patient 5, Count 11, Hydromorphone, 6.8.22, Medical Record, GX 105

Reasons for Prescribing Hydromorphone on 6.8.22:

- Patient's Pain Management Needs: The patient reported significant pain, for which they were taking methadone (10 mg twice daily) and hydromorphone (4 mg as needed). GX105: 172. These medications were part of a broader pain management regimen which pre-existed Dr. Norris' involvement with Patient 5 aimed at alleviating the intense discomfort the patient experiences.

- Diagnosed Conditions:

  - Degenerative Disc Disease: This condition caused chronic pain in the cervical and back regions, necessitating effective pain control measures.

  - Severe Arthritis and Bilateral Hip Issues: These further contribute to the patient's pain, especially in weight-bearing activities.

  - Post-Surgical Foot Pain: The patient had undergone two prior surgeries on the right foot to address Haglund's deformity, but continued to experience bilateral foot pain and required medication to manage it.

- Obesity and Activity Limitation: the patient suffered from obesity, which exacerbated pain and limited physical activity. Pain management was crucial to enable Patient 5's participation in weight management and exercise programs at the YMCA.

These reasons outline the critical needs for pain management with hydromorphone, given the patient's complex medical history and ongoing challenges with chronic pain, obesity[15] and mobility.

b. Patient 5, Count 15, Methadone, 6.28.22, Medical Record, GX 105

The records reflect that the day *before* this prescription was filled that Dr. Norris limited Patient 5's prescriptions. On June 27, 2022, Patient 5 had an appointment, where he demanded dilaudid, claiming he could not complete physical therapy without it. GX 105:142. Dr. Norris declined the same and refilled his methadone prescription.

Patient 5 indicated there are "not enough meds to make it to tomorrow." GX 105:142. Dr. Norris indicated in records that he was playing games, wanting an early refill on his methadone which she declined, indicating that he needed to wait until the next day, when his prescription was due. GX 105:145. That regular methadone refill is made on June 28, 2022, comprising Count 15.

It was not until *June 29, 2022* when Dr. Norris learned Patient 5 was non-compliant on toxicology tests. GX105:152. On July 7, 2022, he was told to come into the office for a random toxicology test and pill count. Patient 5 did not show up.

[15] The Government's expert Timothy King made no analysis of how Patient 5's significant obesity could alter the analysis of whether Dr. Norris' prescriptions—presumed to be proper—were appropriate. Put simply and ignoring the other health and mobility factors, the larger the patient, the more medication is necessary to receive the benefit. Some medications might not be appropriate for an obese patient in doses which otherwise might be efficacious.

On July 11, 2022, Patient 5 tried to reengage Dr. Norris once again. GX105:157. Dr. Norris told Patient 5 he was not safe and needs to go to the clinic. He was discharged. Thus Dr. Norris acted appropriately within what can be shown to be her subjective knowledge.

c. Patient 5, Count 16, Methadone, 7.18.22, Medical Record, GX 105

This medication prescribed was merely to bridge Patient 5 to the clinic. It is written on July 15, 2022. Patient 5 has indicated that he was going to the clinic. Dr. Norris noted:

> Documentation of the off hours line exchange between self, staff and patient. Have reinforced that patient is not being punished by my discontinuing prescription of methadone for pain, but that I am reinforcing safety. That if he is using medications other than the way they are prescribed, or if he is using other drugs on top of the prescriptions, I cannot be responsible for his safety. I gave him the opportunity to have a second chance and demonstrate that he could be safe and he demonstrated by tox test and by inability to attend a pill count that he was too high risk. He continued to focus on how "being a fat person" meant he didn't clear the fentanyl as quickly and that he had not used, but it was reiterated that I was not just taking that into account, it was a combination of factors, and that his BMI is really not a factor in clearing fentanyl.

GX 105:170.

Dr. Norris consistently monitored Patient 5's overall health status, adapted treatment plans as necessary, refused to prescribe him additional medication and ultimately discharged him as unsafe.

It is irrefutable that Dr. Norris was not acting like a drug dealer, nor facilitating addiction or recreational abuse. She offered other options the patient rejected to help prevent or alleviate his symptoms, while keeping him safe (hence the Suboxone prescription). She also discharged him. Subjective intent is not met by these records, nor this history of treatment.

II. SUMMARY OF WITNESSES AND EVIDENCE RELATED TO INTENT

A. ANDREW DAVIS, OPTUMRX

The Government put on Andrew Davis, a pharmacy benefits manager for OptumRx. OptumRx manages the claims for United Healthcare, which was the insurer for Patient 1.

The Government admitted letters from OptumRx to Dr. Norris' office regarding Patient 1. Those letters say:

> This report does not take into account patient-specific variables that may factor into your prescribing decisions. If you have already identified the concern, please **disregard this notice** and continue to monitor your patient for any potential issues.

See GX 502 (emphasis added).

These letters are constantly auto-generated by insurers to providers. The Government, however, tries to impute a nefarious intent to Dr. Norris in not presenting these letters in response to the Board complaint. This does not make sense. Dr. Norris received a subpoena for six patients for their *medical records*. The jury should not have been able to infer guilt based on that fact.

Maine statutes refer to medical records as "treatment records." Maine statutes related to access to those records from health care practitioners include "records related to the patient's diagnosis, treatment and care performed by the health care practitioner." 22 M.R.S.A. §.1711-B(1)(B). Insurance company letters are not treatment records, nor medical records of any sort, so they were not provided. The jury heard no evidence that Dr. Norris saw the letters. Further, as we know from Dr. Brandt, these insurance company letters are very common.

> Q. And just as a doctor, as a practicing doctor, do you ever get auto-generated notices from pharmacies and/or insurance companies, things like that?

> A. Yes. That's fairly common for any number of medications. So right now my practice is in geriatrics and nursing homes. And so I'll get routine pop-ups from the electronic health record or alerts from pharmacies that a patient may be on a medication combination that changes your heart conduction or things like that. They're an alert to double-check yourself. And then there's an area for comment to state whether you agree or do not with any change of care the pharmacy offers and why.

[T. 1219-1220].

No reasonable inferences as to Dr. Norris' subjective intent to commit the crimes can be drawn from these records.

B. DR. ELIZABETH MOCK, MAINE PRESCRIPTION MONITORING PROGRAM

Dr. Mock testified that the Maine Prescription Monitoring Program ("PMP") wrote Dr. Norris a letter indicating that her prescribing practice was different from other practitioners. This is found at GX219.

However, the date of that warning letter was October 12, 2022. The latest charged offense is July 18, 2022. Even if the PMP letter *could* inform Dr. Norris' subjective intent prospectively, it could not do so retrospectively. The Mock testimony and the admitted PMP letter cannot establish notice, because Dr. Norris would have to have had the subjective intent at the time of the offense, of course. Therefore, no permissible inference can be drawn from this evidence because of the failure of the relevant timeframe.

Moreover, while the Government contends that the patients engaged in pharmacy shopping relative to their prescriptions (see T. 575), we know that is no longer a concern due to the PMP. As Dr. Mock noted,

> A. Controlled substance prescriptions that people receive generally at a pharmacy. So if you go to a pharmacy and get a little orange bottle for yourself or your family member, then that is tracked if it's a controlled substance…
> Q. And so, Dr. Mock, you talked about the orange bottle at the pharmacy, right. How does the data regarding that prescription become inputted into the database?
> A. When the prescription is received at the pharmacy, the pharmacy enters it into their database, and then every night after midnight any prescription that is sold, so only prescriptions that are picked up by patients or family members, get uploaded to a national clearinghouse…
> Q. And so for a prescription that's picked up, what kind of information is put into the PMP?
> A. The information about the patient, the name and date of birth, address; the prescription itself, the name of the medicine, the dose, the quantity; and then there's a calculation for the days supplied, so how many days should that prescription last for the patient.

[T. 60-61].

The PMP effectively eliminates the chance of pharmacy shopping. No inferences may be drawn from the PMP testimony and exhibits.

C. WALMART AND PHARMACIST LORI MCKEOWN

The Government put on evidence from Walmart. This included testimony from Russell Baer and Pharmacist Lori McKeown.

Russell Baer indicated that the process of the central block put on Dr. Norris is unknown:

> Q. That central block process is a secret process, isn't it?
> A. It's a process handled under legal privilege. It's not secret.
> Q. Handled under legal privilege means I don't have access to it, right?
> A. I don't even have access to it.
> Q. Right.

[T. 213-214].[16]

However, Mr. Baer also testified that Dr. Norris contested the block and provided her reasons for her prescribing. [T. 215]. This plainly negates any possible inference that Dr. Norris had the subjective intent to act outside of her authorization, if such inference were ever warranted from the Walmart evidence.

Further, the Walmart block letter does not inform a doctor, nor even remotely allege, their view that a crime was committed. The letter indicates:

> In our efforts to meet our compliance obligations, our pharmacist's corresponding responsibility under 21 CFR §1306.04, and to help combat prescription drug abuse and diversion, we routinely review the prescribing patterns and practices of the prescribers whose prescriptions are presented to us for filling. In reviewing your controlled substance prescribing patterns and other factors, we have determined that we will not be able to continue filling your controlled substance prescriptions. We will continue to review information related to controlled substance prescribing and will inform you if our policies change. We regret any inconvenience this may cause to you or your patients.

GX 301.

The Walmart block letter does not discuss the potential for a criminal violation, it does not even suggest it, nor does it provide a specific understanding to the reader as to what Walmart—the corporation, not any individual doctor—disagrees with. Notably, the letter even suggests that Walmart might reverse its position based on information beyond that of the pattern of the prescriber—that might include (but we don't know) the relevant medical literature which Dr. King was forced to admit had, in fact, changed. If subjective intent is to

[16] Where the witness himself is unable to explain the very things he was called to testify about, the defendant faces a confrontation clause challenge. She is rightly permitted to cross-examine the witness, but the witness cannot answer the questions on cross examination. The jury is left with information it cannot properly evaluate and the defendant has an incurable due process issue because she cannot even reach whether the Corporate Block was testimonial.

come from the Walmart letter, the inference is too far removed and unfair to Dr. Norris especially in light of Mr. Baer's ignorance of the "why" of the block. The only way Dr. Norris could have possibly addressed the Walmart letter and avoided criminal liability now based on its vague warning would have been to stop practicing medicine entirely, but even then she might not escape liability for prescriptions she had already issued. Of course, even then she would be doing so with no guidance nor reasoning from Walmart.[17] All Walmart did was inform Dr. Norris it disapproved of her general statistical metrics likely to avoid another costly civil lawsuit like the ones it has had settled to date.

Lori McKeown, who was the Walmart pharmacist, indicated she could not reach Dr. Norris when refusing to fill a prescription for Patient 2. Instead, she left a message for Nancy Drown. [T. 173]. Even if Dr. Norris was told about this refusal, that communication could not be inferred to supply Dr. Norris with the requisite *mens rea* to act outside her authorization for the same reasons that it lacked specificity or context. Moreover, it would have been effective—if it was for any legal purpose—only after the "warning" was communicated. Of course, because of the subjective application of *Ruan*, even a specific warning (unlike what was done here)

[17] Which application goes far beyond even Walmart's intent in issuing the letter. There is nothing to suggest, and no evidence was presented establishing that Walmart had any specific concerns about individual prescriptions but rather, as the letter suggests, merely a "pattern" ascribed to Dr. Norris. The nature of criminal charges generally and that of a doctor prescriber especially after *Ruan* make clear that if Dr. Norris is to be held to account criminally for her prescriptions, it is to be specific ones for specific reasons. The Government here has not—because it cannot—even establish that Walmart was aware of and considered in its decision to issue a corporate block, a single prescription related to the charges against Dr. Norris. To allow the Walmart block to imply even an inference of subjective knowledge or guilt is to undermine the foundation of the American system of justice where a defendant is innocent unless or until proof beyond a reasonable doubt is established as to specific conduct.

to the doctor, is necessarily insufficient for criminal culpability. Even then, the warning would be done by a pharmacist, not a physician, whose roles, training, education and experience with the individual patient at issue are markedly different.

We know the prescription McKeown questioned was filled, of course, by another pharmacist. [T. 1325]. If McKeown's testimony is to provide an inference, the opposite inference as to lack of *mens rea* must be supplied when another pharmacist decided to fill it after the warning was issued (if it was). Furthermore, even if a pharmacist's view about an individual prescription could supply Dr. Norris' subjective *mens rea* to act beyond her authorization, which is doubtful, it would only apply to Patient 2 here.[18]

D. ERIN COSTELLA

Erin Costella testified related to the Northeast Unified Program Integrity Contract ("UPIC") data. Costella made a request to Dr. Norris for records related to Medicaid billing. Dr. Norris' billing person, Russell Denner, handled the response to the request. [T. 234]. UPIC became concerned that Denner provided records that were incomplete. [T. 236]. While Ms. Costella testified that she tried to reach Dr. Norris through a number of ways, it appears she had contact information for the wrong Dr. Norris:

[18] The prosecution here has failed to explain how or why a jury should have balanced the various levels of knowledge and experience in its wholly circumstantial case. A corporation and a pharmacist or a medical board's retired secretary, even if properly informed, have no business defining the best medical practices for a doctor specializing in pain management treatment. Dr. King, though in some ways an equal to Dr. Norris, testified he knew nothing about how medicine is actually practiced in Maine and therefore he was not qualified to state whether Dr. Norris was "acting in the usual course of [her] professional practice." 21 C.F.R. § 1306.04(a).

> Q. And so on 5/23 of '22 you indicate that you called Graceful Recovery at a 212 area code, right?
> A. Yes.
> Q. And that is an area code for the state of New York, correct?
> A. Okay…
> Q. Okay. And you indicated that at that 212 number is when you heard a voicemail stating when Dr. Norris' office was open, what hours of operation her medical office was, right?
> A. Yes, that's correct.
> Q. And that was directly related to the 212 call, right?
> A. Yes.

[T. 213-214].

No inferences can be plausibly drawn from Ms. Costella's testimony. At best, Dr. Norris received her inquiry, had her billing person handle the request and when Ms. Costella attempted to follow up, she called the wrong Dr. Norris. While Ms. Costella also testified she tried to reach the Defendant on social media, she did not ascertain whether it was the right Dr. Norris she contacted or not. Regardless, no plausible inferences can be drawn from the Costella testimony or exhibits in light of the specific subjective *mens rea* requirements at issue in this matter. Vague concerns about incomplete billing records—even if communicated directly to this Dr. Norris, do not, and importantly cannot, create an inference of subjective awareness that the several prescriptions at issue here were outside Dr. Norris' usual course of professional practice and without a legitimate medical purpose, when she already wrote prescriptions for the controlled substances.

E. EMMA HINNIGAN

Agent Hennigan cannot supply *mens rea*. In fact, we know through her and through Elizabeth Strout, that the Board investigated and dismissed the complaint

and investigation against Dr. Norris, affirmatively thanking her for her work. That investigation involved Dr. Norris and her response explaining her prescribing methodology.

Counsel submits that the Government has played fast and loose with the Board investigation, using it as a basis for invading patients' and Dr Norris' privacy. In their opening statement, for example, the Government referenced the Board Complaint and the Dr. Norris response, but not the resultant dismissal. This mirrors a pattern for which the Government was already chastised in pre-trial orders. If the jury was to make inferences from the Board's investigation it comes from that dismissal (Defendant's Exhibit 4c). The inference is that the Board essentially told Dr Norris "keep up the good work!" (something the jury heard was specifically requested by the Board and not in its usual dismissal template). That undermines not only the inference that being investigated by the Board (after the fact) shows an intent to violate the law, but also negates the actual proof, if there ever was any.

This is not a typical "drug dealer" case. As we know from *Gonzales v. Oregon*, 546 U.S. 243 (2006), "The statute and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally." *Id*. at 270. The Board dismissal shows that medical personnel in Maine understood that Dr. Norris

had reasons for her prescribing that the Board approved of. Agent Hinnigan does not supply evidence of Dr. Norris' subjective intent to act beyond its authorization.

F. DR. TIMOTHY KING

Dr. King's testimony can be summarized in this question and answer:

> Q. Dr. King, for the prescriptions that we've discussed that Dr. Norris issued, prescriptions we discussed yesterday and the prescriptions we discussed today, in your opinion was Dr. Norris practicing medicine when she issued those prescriptions?
> A. No. The records do not represent the legitimate practice of medicine.

[T. 705].

While that opinion is hotly contested by the defense, the issue on this motion is whether Dr. King could opine on Dr. Norris' subjective intent. Quite plainly he could not. What he could do is merely define the objective parameters of Dr. Norris' practice area, something he failed to do admitting he did not consider the relevant geographical area.

In *Diaz v. United States*, 602 U.S. ___ (2024), an opinion that was announced on June 20, 2024 during this trial, the Supreme Court emphasized this point. There, a Homeland Security agent testified that drug couriers carrying large quantities of drugs are generally aware of the presence of the drugs. The Court's ruling is that "[a]n expert's conclusion that '*most* people' in a group have a particular mental state is not an opinion about 'the defendant' and thus does not violate Rule 704(b)."[19] Maj. Op. at 11 (emphasis added). It does not address

[19] Federal Rule of Evidence 704(b) provides that "[i]n a criminal case, an expert witness must not state an opinion about whether the defendant did or did not have a mental state or condition that constitutes an element of the crime charged or of a defense."

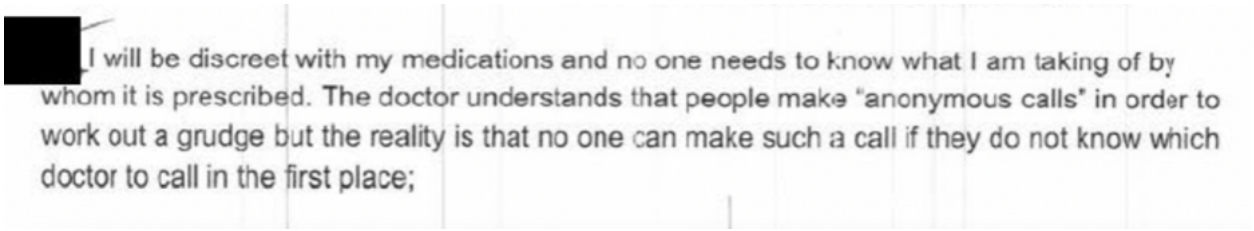
whether an expert can say that a person "almost always" know[s]" or that "[i]n my experience, 99% of drug couriers know." Gorsuch, J., dissenting at 8. The majority agrees that the government's expert cannot testify that "all couriers know," *see* Maj. Op. at 9, or that "that a hypothetical person who matches the defendant's description will have the mental state required for conviction," Gorsuch, J., dissenting at 6.

As the Supreme Court has recognized, expert opinions about the defendant's "state of mind at the crucial moment" when committing a criminal act may "easily mislead" the jury into "thinking the opinions show more than they do." *Clark v. Arizona*, 548 U.S. 735, 776 (2006). The risk of unfair prejudice can be exacerbated, too, where, as here, the professed expert "carries with [him] the imprimatur of the [g]overnment." *United States v. Young*, 470 U. S. 1, 18 (1985). A witness like that "may induce the jury to trust [the witness's] judgment rather than its own view of the evidence." *Id*., at 18–19; *see also United States v. Scheffer*, 523 U.S. 303, 314 (1998) (plurality opinion) (experts like these may attain an "aura of infallibility").

No inferences nor facts concerning Dr. Norris subjective *mens rea* can be inferred from Dr. King's testimony, and because of that fact and the failure to present evidence of Dr. Norris' subjective state of mind, the jury went beyond what is reasonable in convicting Dr. Norris. There were no reasonable inferences from which the jury was able to find beyond a reasonable doubt that Dr. Norris had the relevant *mens rea* sufficient to defeat her authorization to write prescriptions for controlled substances.

G. THE CONTROLLED SUBSTANCES AGREEMENT

Finally, much was made by the Government of a single provision of the Graceful Recovery Controlled Substances Agreement (found in the patient records, GX101, GX102, GX103, GX104 and GX105). By highlighting but one sentence from voluminous patient records the Government suggested an inference of subjective *mens rea*. This inference, however, was stretched too thin to convict Dr. Norris. A single provision of the agreement the Government contests is as follows:[20]


[redacted] I will be discreet with my medications and no one needs to know what I am taking of by whom it is prescribed. The doctor understands that people make "anonymous calls" in order to work out a grudge but the reality is that no one can make such a call if they do not know which doctor to call in the first place;

While the Government tries to stretch this into advice for patients not to inform on each other, the opposite inference is much more plausible. Given Dr. Norris' patient population, one can easily infer just what is said in the provision: that when people get mad at each other, they can call the doctor to try to stop their prescriptions, but only if they first know about them and who is prescribing them. Dr. Norris' admonition to "be discreet" seems awfully reasonable and shows nothing

[20] Analyzing this language shows that its author—one cannot know who that was—has focused on what the patient experiences. It shows no subjective intent of the "doctor" mentioned. As it is written, the patient is asked to consider that if (s)he is "discreet" about what medications (s)he takes no one will interfere with his/her treatment as a form of retaliation for a "grudge." Many patients, one hopes, need not worry about this happening. However, for the few that have people who might hold grudges against them, the advice is simply that if the grudge-holder does not know who the prescribing professional is, the grudge-holder has no path to interfere. Assuming it can be considered a statement of Dr. Norris, the most it can be said to show is that "the doctor" hopes the patient will not open themself up for needless retaliation for grudges. Ironically, it is the Government here that has—perhaps improperly—interfered with the treatment records of many patients by demanding confidential information. The "Controlled Substances Agreement" merely reflects legal rights provided by federal law, to confidentiality for patients and in no way impeded—as is amply demonstrated by the actual investigations into Dr. Norris—any legitimate evaluation of what prescriptions Dr. Norris was issuing.

regarding her subjective intent in issuing prescriptions other than to allow the patient to enjoy privacy afforded by the doctor-patient privilege: something that cannot be said to be either outside the scope of a doctor's practice or lacking in medical purpose (and no one has testified that it does).

Moreover, this provision encourages the patients to assert their medical and substance use privileges related to these controlled substances. To stretch this inference the way the Government does here is outrageous and certainly does not supply evidence of Dr. Norris' subjective intent to violate her authorization beyond a reasonable doubt.

H. Addiction Medicine Doctors Need To Consider Harm Reduction When Treating Patients

The treatment of patients with Substance Use Disorder often presents conflicting choices. It is not merely a choice of a direct "good" or "bad" result, but often involves picking the best of several unattractive choices. This concept of "harm reduction," is a central pillar of the United States Department of Health and Human Services' Overdose Prevention Strategy[21]. Harm reduction strategies try to find better ways to treat patients with Substance Use Disorder by keeping them alive, improving health outcomes and working to improve safety. An example of this philosophy might be giving an intravenous drug user clean needles to prevent infectious diseases. While critics may say that giving clean needles encourages further drug use, addiction medicine doctors know this is part of a basic harm reduction strategy. Accordingly,

[21] https://www.hhs.gov/overdose-prevention/

> Harm reduction is an evidence-based approach that is critical to engaging with people who use drugs and equipping them with life-saving tools and information to create positive change in their lives and potentially save their lives.

Substance Abuse and Mental Health Services Administration[22].

As the Court can easily glean from the exhibits and testimony, Dr. Norris' patients' often presented with a combination of addiction and chronic pain problems. This makes the drawing of inferences largely ineffectual, given that Dr. Norris might be continuing to treat chronic pain despite an aberrant urine drug test result, or the presence of alcohol. She might choose to change a prescription to methadone to reduce euphorigenic potential, while providing stable pain control in order to reduce relapses or cravings. This harm reduction philosophy means continuing to work with patients who sometimes exhibit behaviors or actions that are risky, because discontinuing treatment is *more risky*.

This harm reduction philosophy undermines the inferences the Government presses to convict Dr. Norris. When faced with the lesser of two evils, Dr. Norris continued to try to help her patients. While she plainly did not endorse all her patients behaviors—and indeed discouraged them—it cannot be that an OptumRx letter or a WalMart pharmacist declining to fill a prescription infers that she intends to behave in an unauthorized manner. Rather, it is part of a harm reduction strategy, endorsed by the United States Department of Health and Human Services.

[22] https://www.samhsa.gov/find-help/harm-reduction

III. THE GOVERNMENT DID NOT PROVE DR. NORRIS' SUBJECTIVE INTENT TO EXCEED THE SCOPE OF HER AUTHORITY AND THE JURY VERDICT MUST BE SET ASIDE

As the Supreme Court made clear in *Ruan*, the Government bears the burden of "proving that a defendant knew or intended that his or her conduct was unauthorized." *Ruan*, 142 S. Ct. at 2382. This is so because unless a prescribing doctor uses their "prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood" the federal government has no interest in, or mechanism to, regulate the practice of medicine generally. *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006). "*Ruan* clarified that once a defendant produces evidence that he falls within the authorization exception,[23] the Government has the burden of proving lack of authorization—that a defendant knew or intended that his conduct was unauthorized—beyond a reasonable doubt." *United States v. Bauer*, 82 F.4th 522, 528 (6th Cir. 2023) .

On remand from the Supreme Court, the Tenth Circuit made clear that §841's *mens rea* applied to authorization itself, not the regulatory criteria. *United States v. Kahn*, 58 F.4th 1308, 1316 (10th Cir. 2023) ("*Kahn II*") ("*Ruan* treats the two criteria in §1306.04(a) not as distinct bases to support a conviction, but as 'reference to objective criteria' that may serve as circumstantial evidence of a defendant's subjective intent to act in an unauthorized manner."). It is therefore insufficient to prove that an otherwise authorized medical defendant intentionally or knowingly acted without a legitimate medical purpose or outside the usual course

[23] Which fact was stipulated to prior to trial here and certainly even if not stipulated to was established by testimony during the trial.

of professional practice. *Id*. at 1316 ("[T]he jury instructions were erroneous because they allowed the jury to convict Dr. Kahn after concluding either that Dr. Kahn subjectively knew a prescription was issued not for a legitimate medical purpose, **or** that he issued a prescription that was objectively not in the usual course of professional practice. Both approaches run counter to *Ruan*.") Rather, the Government must prove that Dr. Norris subjectively knew that she was legally unauthorized to issue a given prescription. *Id*., at 1317. ("The question to be posed to a jury is whether a physician was subjectively intending to act in a way that he believed was unauthorized—not whether he was attempting to act in a way that a reasonable physician should believe was authorized or unauthorized."). The reason for this conclusion is clear: "a knowing failure to act outside professional norms was not equivalent to a knowing failure to act without authorization." *Dunn v. Smith*, No. 22-2082, 2023 WL 2770960, at *5 (10th Cir., Apr. 4, 2023) (discussing *Kahn II*).

The Tenth Circuit's articulation of § 841's *mens rea* cleaves to the *Ruan* opinion. *Ruan* focused on the "statutory clause ('[e]xcept as authorized')," *Ruan*, 142 S. Ct., at 2379 (alteration in original), not the regulatory requirements for a valid prescription. The Supreme Court explained that the "statutory clause … plays a critical role in separating a defendant's wrongful from innocent conduct[]" and "conclude[d] that the statute's mens rea applies to that critical clause." *Id*. (emphasis added).

The *Ruan* Court illustrated its holding by discussing *Liparota v. United States*, 471 U.S. 419 (1985), which addressed the *mens rea* required to convict a person for unauthorized use of food stamps:

> Analogous precedent reinforces our conclusion. In *Liparota*, we interpreted a statute penalizing anyone who "'knowingly uses (food stamps) in any manner not authorized by'" statute. We held that "knowingly" modified both the "use" of food stamps element and the element that the use be "not authorized." We applied "knowingly" to the authorization language even though Congress had not "explicitly and unambiguously" indicated that it should so apply. But if knowingly did not modify the fact of nonauthorization, we explained, the statute "would ... criminalize a broad range of apparently innocent conduct."

Ruan, 142 S. Ct., at 2378 (internal citations omitted).

In *Liparota*, the "Supreme Court held that knowingly engaging in conduct that is, in fact, unauthorized is not sufficient, even if one is aware of all the factors that render it unauthorized. Instead, the government was required to prove that the defendant actually knew that his conduct was unauthorized under the law." *Kahn II*, 58 F.4th at 1315 n.3 (*discussing Liparota*, 471 U.S., at 429-30); *see also Liparota*, 471 U.S., at 429 ("Requiring knowledge of illegality in a § 2024(c) prosecution is allegedly necessary to avoid this kind of vicarious, and nonfault-based, criminal liability.").

Subjective knowledge of a criminal violation is distinct from and cannot be replaced by, the objective criteria that explains the criminality. Notably, "Just as in *Liparota*, to convict under § 841(a) of the CSA, 'the Government may prove by reference to facts and circumstances surrounding the case that petitioner knew that his conduct was unauthorized or illegal.'" *Kahn II*, 58 F.4th at 1315 (*quoting*

Liparota, 471 U.S. at 434). "However, the government's showing of objective criteria, without proving that a defendant actually [subjectively] intended or knew that he or she was acting in an unauthorized way, is not enough to convict." *Id*. Instead, "[t]he government must prove that a 'defendant knew or intended that his or her conduct was unauthorized[.]'" *Kahn II*, at 1314.

The necessary evidence of the Defendant's subjective intent is plainly lacking and, as caselaw shows, cannot be supplied by any amount of objective criteria.[24] In order to convince the jury to convict Dr. Norris here the Government stretched inferences it was not entitled to until they were so thin they disappeared. This Court must act to set aside this wrongful verdict.

Dated this 3rd day of July 2024 in Portland, Maine.

Respectfully submitted,

/s/ Timothy E. Zerillo
Timothy E. Zerillo, Esq. (Bar No: 009108)
ZERILLO LAW FIRM, LLC
1250 Forest Avenue, Ste 3A
Portland, ME 04103
207-228-1139
tim@zerillolaw.com

/s/ Amy Fairfield
Amy Fairfield, Esq. (Bar No: 009598)
Fairfield & Associates, P.A.

[24] One of the issues presented to this Court is the lack of clear guidance from the *Ruan* court. It is true that *Ruan* suggests the Government "can prove knowledge of a lack of authorization through circumstantial evidence," and that ":the scope of a doctor's prescribing authority" remains tethered to "objective criteria such as `legitimate medical purpose' and `usual course' of `professional practice.'" *Ruan* 142 S. Ct. at 2382. Yet *Ruan* also holds that "the statute's `knowingly or intentionally' mens rea applies to authorization," such that "[a]fter a defendant produces evidence that he or she was authorized to dispense controlled substances, the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so.". *Ruan*, 142 S. Ct. at 2375. Thus, *Ruan* clearly allows, and perhaps requires, some balance of objective and subjective fact.

10 Stoney Brook Lane
Lyman, ME 04002
207-985-9465
amy@fairfieldandassociates.com

Counsel for Defendant Dr. Merideth C. Norris, D.O.

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

UNITED STATES OF AMERICA	)	
	)	
v.	)	**CRIMINAL NO. 2:22-cr-00132-NT**
	)	
MERIDETH C. NORRIS, D.O.	)	

CERTIFICATE OF SERVICE

I, Timothy Zerillo, hereby certify that I have caused to be served via ECF the **DEFENDANT'S MOTION FOR JUDGMENT OF ACQUITTAL AND RENEWAL OF CHALLENGE FOR VAGUENESS.**

Dated this 3rd day of July 2024 in Portland, Maine.

Respectfully Submitted,

ZERILLO LAW FIRM, LLC

/s/ Timothy E. Zerillo, Bar No. 9108
Attorney for Dr. Merideth Norris
1250 Forest Avenue, Ste 3A
Portland, ME 04103
tim@zerillolaw.com